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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,794	01/30/2007	Venkataraman Sundaram	BULK 3.3-086	6787

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EXAMINER

CHANDRAKUMAR, NIZAL S

ART UNIT	PAPER NUMBER
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1625

NOTIFICATION DATE	DELIVERY MODE
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04/01/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

Office Action Summary	Application No. 10/595,794	Applicant(s) SUNDARAM ET AL.	
	Examiner NIZAL S. CHANDRAKUMAR	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 15-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 20-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/28/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 02/12/2009 is acknowledged. The traversal is on the ground(s) that the logical foundation of the restriction requirement is faulty. Applicant's traversal is fully considered and is partially persuasive. Accordingly claims 1-14, and the newly added claims 20-26 are examined together. Claims 15 and dependent claims 1819 (Group 3) drawn to resolution of citalopram is not examined and the restriction/requirement with respect to these claims is proper for the following reasons: .

Applicants argue that the starting material for the process of claim 15 is prepared in step (b) of claim 1 or in step (a) of claim 8. As such, the instant election requirement obviously has not involved the "broad, practical consideration" as provided in MPEP 1850.

However, the inventions of the group (claims 1-14 and claims 20-26) and group (claims 15-19), do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The special technical feature common to these groups, considered as a whole, is the chiral compound escitalopram. This chiral compound is not a contribution over the prior art because it is well known in the prior art.

Boegesoe et al. (US 4943590, See abstract) describe preparation of this chiral compound.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-19 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/12/2009.

This application contains claims 15-19 drawn to an invention nonelected with traverse in the reply filed on 02/12/2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 21 (and dependent claims 2-7, 9-14, 21-26) and claim 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 8, and 21 recite the term 'hydrolyzing'. The commonly accepted meaning of this term contradicts what appears to be intended here. Given that no special definition of this term is found in the specification, it is suggested that this term be replaced with terms consistent with the liberation of the free amine from the salt.

Claim 20 is drawn to a compound made by the methylation of an amine. The structure of the starting material amine being methylated, whether it is a primary amine or a secondary amine is not clear even though the structure of the end product escitalopram is clear.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, 21 (and dependent claims 2-7, 9-14, 21-26) and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for making escitalopram by a specific multi-step process using specific reagents and conditions, does not reasonably provide enablement for multiple possibilities of

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reagents and reaction parameters for the first step (step a)). For instance, disclosure is found for conditions for carbon alkylation (step a) Reaction conditions describing a large number of bases and solvents for generating the required intermediate dihydrobenzofuran anion and further reaction of this anion with chloropropylamine are disclosed in page 7 and page 8 of the specification. Three working examples wherein one specific base and two solvents are used for this step are disclosed in working Examples 1 and 2 on pages 26 and 27 of the specification. The details of the Examples 1 and 2 with regard to enabling disclosure are discussed below. The preparation of the starting material for step (b) resolution (see Examples 1, 2 and 13 of the specifications) is not disclosed in a manner that would be enabling for one skilled in the art. The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the relevant factual considerations.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: (1) breadth of the claims; (2) nature of the invention; (3) state of the prior art; (4) amount of direction provided by the inventor; (5) the level of predictability in the art; (6) the existence of working examples; (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure; and (8) relative skill in the art.

The invention relates to a process of preparing escitalopram involving mainly three step process.

All of the above mentioned Wands factors have been considered with regard to the first step a), with the most relevant factors discussed below:

Step a) of independent claims 1, 8 and 21: Disclosure of this step a) (see Example 1, 2 and 13 of specification) lacks necessary information with regard to one of the reactants, 3-chloropropylamine. The specification is silent with regards to how to prepare this compound. There is also no direction or guidance in the form of prior art citations (commercial or literature) in the specification on how to make or use this compound. The artisan would predict that 3-chloropropylamine would be unstable, forming linear and cross-linked polymers, and neither the specification nor the prior art teach how to prepare this compound (in free base form) to avoid such a polymerization and further use it in carbon-alkylation reaction. Example-2 discloses the use of acetone as solvent in the alkylation step a). The artisan would predict that the base necessary for the generation of the intermediate isobenzofuran anion would be unavailable because the base is expected to be consumed by the solvent molecules. The guidance, direction and working example with respect to this first step of the process is not described in adequate detail and one of ordinary skill in the art would be faced with difficulty

With regards to claim 12, 20: Claims are drawn to (impurity) formamide in the escitalopram free base. Disclosure in the specification is found for removing the (impurity) formamide by washing the escitalopram oxalate (page 36, last three lines). Direction, guidance or working example for making escitalopram containing less than

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0.01% formamide is not found in the specification. Example 5 in which the preparation of Escitalopram is disclosed is silent with regards to the claimed formamide.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIZAL S. CHANDRAKUMAR whose telephone number is (571)272-6202. The examiner can normally be reached on 8.30 AM - 4.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571 0272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nizal S. Chandrakumar

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625

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